



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,132	08/28/2006	Patrice Richard	Q94512	8183
23373 7590 02/03/2011 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER SU, SUSAN SHAN	
			ART UNIT 3761	PAPER NUMBER
			NOTIFICATION DATE 02/03/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM



UNITED STATES PATENT AND TRADEMARK OFFICE

*Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov*

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/577,132
Filing Date: August 28, 2006
Appellant(s): RICHARD, PATRICE

Dion R. Ferguson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5 November 2010 appealing from the Office action mailed 1 September 2009 (as modified by Advisory Action of 1 December 2009).

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

1-10, 12, 13, 15-17, and 19.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

Claims 1, 2, 7, 9, 13, 16 are rejected over Dracker (US 5,356,373) under 35 USC 102(b). Claims 3-6 are rejected under 35 USC 103(a) for being obvious over Dracker in view of Deverre (US 7,131,958). Claim 8 is rejected under 35 USC 103(a) for being obvious over Dracker in view of Darling (US 6,213,986). Claim 10 is rejected under 35

USC 103(a) for being obvious over Dracker in view Van Der Heiden (US 5,879,318).

Claims 12, 15, 17 & 19 are rejected under 35 USC 103(a) for being obvious over Dracker in view of Seddon (US 6,024,731). **Thus, claims 1, 7 and 9 previously rejected under 35 USC 103 (a) are now rejected under 35 U.S.C. 102(b) over previously used reference.**

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,356,373	DRACKER	10-1994
6,024,731	SEDDON ET AL.	2-2000
7,131,958	DEVERRE	11-2006
6,213,986	DARLING, JR.	4-2001
5,879,318	VAN DER HEIDEN ET AL.	3-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 7, 9, 13, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dracker (US 5,356,373).

With regard to Claim 1, Dracker teaches a placental-blood extraction device (Abstract discloses an apparatus) comprising at least one extraction needle (Col. 4 lines 32-33) for piercing the vein of the umbilical cord or of the placenta (Col. 4 lines 31-32), a collection vessel (62) connected to said at least one needle via at least one tube (66), and suction means (box shown in Fig. 2 and the vacuum source implied in Col. 3 lines 17-21 and 41-46) connected to said at least one needle (through expansion of collection bag 62) for sucking the placental blood so as to feed said collection vessel;

wherein said suction means comprises a vacuum bottle that simultaneously forms a collection vessel (the box shown in Fig. 2 is broadly interpreted to be a bottle, since it contains the bag 62, it is also a collection vessel).

With regard to Claim 2, Dracker also teaches that said suction means further comprises a vacuum pump ("suction means" disclosed in Col. 3 lines 17-21; "pump" is broadly defined as "a device that raises, transfers, delivers, or compresses fluids or that attenuates gases especially by suction or pressure or both," refer to merriam-webster.com).

With regard to Claim 7, Dracker also teaches that the device includes blood-flow control means or suction control means ("pipe tap" in Col. 6 lines 15-17).

With regard to Claim 9, Dracker also teaches that the collection vessel contains an anti-coagulant before receiving the placental blood (Col. 2 lines 60-63).

With regard to Claim 13, Dracker teaches a placental-blood extraction device comprising:

an extraction needle (Col. 4 lines 32-33) for piercing the vein of an umbilical cord or of a placenta,
a collection vessel (combination of box of Fig. 2 and bag 62) in fluid connection with the needle via a tube (66), and
a vacuum (as created through expansion of bag 62, Col. 3 lines 41-46) in fluid connection with the needle so as to feed said collection vessel;
wherein the vessel creates the vacuum (vacuum is created by the expansion of bag 62).

With regard to Claim 16, Dracker also teaches that a pump (applying the broad definition of "pump" as in Claim 2) creates the vacuum (Col. 3 lines 17-21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dracker in view of Deverre (US 7,131,958).

With regard to Claims 3-6, Dracker also teaches at least one injection (broadly defined as "introduce") or extraction (broadly defined as "remove") site (where tube 70 connects to bag 62, see Fig. 3) and that the extraction site is provided on the collection vessel (where tube 70 connects to bag 62) and that it is for extracting blood contained in the collection vessel (Col. 6 lines 34-37). Dracker does not teach that the injection or extraction site is between the extraction needle and the collection vessel. Deverre teaches a placental blood collection system wherein two injections sites (12 or 8, for introduction of either anticoagulant in bag 11 or rinsing fluid from bag 6, respectively, see Fig. 2) are located between an extraction needle (4 or 5) and a collection vessel (1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Dracker with the additional injection sites and the fluids for the purpose of preventing blood coagulation between the needle and the collection vessel.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dracker in view of Darling, Jr. (US 6,213,986, "Darling"). Dracker does not explicitly teach that the blood-flow control means or the suction control means ("pipe tap") include a knurled adjustment wheel. Darling teaches a fluid-flow control means (10, Fig. 1) that includes a knurled adjustment wheel (110, Figs. 2-3). Furthermore, knurled adjustment wheels are commonly used in everyday life for fluid control, such as faucet knobs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify

Dracker with Darling for the purpose of having a way to control the amount of flow with an easy-to-grip means.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dracker in view of Van Der Heiden et al. (US 5,879,318, "Van Der Heiden"). Dracker does not expressly teach that the device is packaged in sterile manner and is assembled in a single package so as to be ready to use once said package has been opened. Van Der Heiden teaches packaging a cord blood collection device in a sterile manner (Col. 6 lines 15-17) and is assembled in a single package that is ready to use (suggested by Col. 6 lines 35-36 because sterility for the entire closed system can be kept only if the system is already closed before the sterilization process and kept sterilized as a single connected system). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Dracker with Van Der Heiden for the purpose of preventing contamination of the device and subsequently the contents inside the device.
5. Claim 12, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dracker in view of Seddon et al. (US 6,024,731, "Seddon").

With regard to Claims 12 & 15, Dracker does not explicitly teach that the vessel/vacuum bottle is of Redon type (through searching literature, e.g. US 5,078,704, "Redon type" bottle is understood to be a rigid bottle pre-charged with vacuum and provided with a pressure indicator and a wound exudate inlet). Seddon teaches a Redon type collection vessel (Col. 5 lines 1-3) used in a medical setting that creates a vacuum in fluid connection with a tube (see Fig. 1) that is adapted for contacting a wound on a patient. It would have been obvious to one of ordinary skill in the art at the

time of the invention to modify the box of Dracker with the Redon bottle of Seddon for the purpose of allowing the practitioner to gauge how much suction is left in the collection vessel and not needing a separate suction source at the time of blood extraction.

With regard to Claim 17, Dracker teaches a method of extracting fluid from an umbilical cord or a placenta (see Fig. 1) comprising:

providing an extraction device comprising an extraction needle (Col. 4 line 32), a collection vessel (box of Fig. 2 and bag 62) in fluid connection with the needle via a tube (66), the vacuum (created by outward expansion of the walls of bag 62) in fluid connection with the needle so as to feed said collection vessel; and
piercing in the vein ("venipuncture," Fig. 1) of the umbilical cord or of a placenta and drawing out fluid with the aid of the vacuum (Col. 3 lines 41-52).

Dracker does not explicitly teach that the collection vessel is of the Redon type. Seddon teaches a Redon type collection vessel (Col. 5 lines 1-3) used in a medical setting that creates a vacuum in fluid connection with a tube (see Fig. 1) that is adapted for contacting a wound on a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the box of Dracker with the Redon bottle of Seddon for the purpose of allowing the practitioner to gauge how much suction is left in the collection vessel and not needing a separate suction source at the time of blood extraction.

Art Unit: 3761

With regard to Claim 19, Dracker also teaches the step of using a pump (applying the broad definition of “pump” as in Claim 2) to aid in the extraction of the fluid (Col. 3 lines 17-21).

(10) Response to Argument

It is first necessary to establish that the instant Application does not provide a limiting definition for what a Redon bottle is. Through extensive searching, it is noted that the clearest description of a Redon bottle is provided in "State of the Art" section of Wejnar (US 5,078,704) which discloses a plastic bottle with a pressure indicator and a connector for a tube leading to a wound drain. The bottle has been subjected to reduction in pressure under sterile conditions. Examiner therefore interprets a bottle pre-charged with vacuum and having a pressure indicator and an inlet for receiving wound exudate to be a Redon bottle.

Appellant argues on pages 12-13 of the Remarks that one skilled in the art would not look to Seddon's teaching of a Redon-type bottle to modify the suction device of Dracker because Seddon's bottle is a passive device whereas Dracker's device is active. Examiner respectfully disagrees. While Seddon's device allows for suction without a pump that is constantly running (either through manual power or electrical power) and Dracker's device allows for a constant suction (e.g. no diminish in vacuum), but both vacuum sources serve the same function of forcibly extracting fluids from the tissue. Therefore the problems that both devices seek to solve are the same and Seddon's device would not be "incompatible" as asserted by Appellant.

Appellant's arguments (pages 13 & 15) regarding the combination of Deverre with Seddon are moot because that rejection has been vacated.

Appellant argues on pages 14-15 that Seddon would teach away from Dracker because Seddon's device is for slowly collecting fluids. Examiner maintains that 1)

Seddon's device is in the same art as Dracker because both teach devices using vacuum to remove fluids from body tissues; 2) Dracker does not explicitly teach against using a vacuum bottle and thus does not constitute as "teaching away" from using a vacuum source that is not constantly powered; 3) Seddon does not explicitly teach that its device is incapable for removing blood and thus should not be considered as teaching away from being combined with Dracker's teachings.

Appellant then argues that since Redon bottle has been known for a long time in wound drainage systems but never used for blood collection, it provides strong secondary evidence that it is not obvious to be combined with a blood collection system. Examiner respectfully disagrees. Since Seddon is shown to be reasonably pertinent to the particular problem with which the Appellant was concerned (e.g. providing suction to remove fluid from body tissues), Examiner maintains that it is proper to rely upon Seddon for rejection of the claimed invention.

(11) Related Proceeding(s) Appendix

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be

relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Susan Su/

Examiner, Art Unit 3761

5 January 2011

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD T HAJEC/

Director, Technology Center 3700

Conferees:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763